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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

TECH CENTER 1600/2900

Applicant : Akiko ITAI et al.

Examiner: Borin

Serial No : 09/700,708
(National Stage of PCT/JP98/02302)

Filed : November 24, 2000
(I.A. Filed May 26, 1998)

Art Group: 1631

For : METHOD FOR PREDICTING FUNCTIONS OF PROTEIN

ELECTION WITH TRAVERSE

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

This is in response to the requirement for restriction under 35 U.S.C. 121 and 372 mailed from the U.S. Patent and Trademark Office on November 27, 2002, which sets a one month shortened statutory period for response. Inasmuch as the one-month shortened statutory period was originally set in the Office Action to expire on December 27, 2002, Applicants hereby submit that this response is timely filed. If for any reason the Commissioner determines that an extension of time is necessary to maintain the pendency of the application, this should be considered to be an express request for any necessary extension of time and authorization for the Commissioner to charge any necessary extension of time fee to Deposit Account No. 19-0089.

RESTRICTION REQUIREMENT

Restriction to one of the following inventions is required under 35 U.S.C. §§ 121 and 372:

- I. Claims 1-4, drawn to database.
- II. Claims 5-8, drawn to alignment method.

In an attempt to justify the requirement for restriction, the Examiner has taken the position that the inventions are distinct, each from the other, and do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features because Group I is the technical feature that links Group I-II, and the requirement asserts that Group I is not the contribution over the prior art because it is suggested by a plurality of references describing protein databases containing functional information, specifically referring to U.S. Patent No. 6,023,659. The Examiner also alleges that inventions II and I are related as process of making and product made, and that the database of Group I containing information about proteins can be obtained by a plurality of other alignment methods in the art.

Election

In order to be responsive to the requirement for restriction, Applicants elect Group II, i.e., claims 5-8, with traverse.

However, for the reasons set forth below, Applicants submit that the restriction requirement is improper, and should be withdrawn, whereby an action on the merits of all of the pending claims is warranted.

Traverse

Notwithstanding the election of the claims of Group II in order to be responsive to the requirement for restriction, Applicants respectfully traverse the requirement.

The Examiner is reminded that in determining unity of invention, the criteria set forth in 37

C.F.R. 1.475 must be considered. Specifically, Applicants note that 37 C.F.R. 1.475 provides:

Unity of invention before the International Searching Authority, the International Preliminary Examining Authority, and during the national stage.

(a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

(d) If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

(e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

Applicants point out that the restriction requirement must state why unity of invention is lacking at least under 37 C.F.R. 1.475(a) and (b). Therefore, the restriction requirement is improper for not discussing the various sections of 1.475.

Moreover, Applicants note that the restriction requirement is incorrect in its characterization of the relationship of the inventions by indicating that the inventions are related as a process of making and product made. In fact, the inventions are directed to a product and a process for using the product.

However, either way the invention is characterized, 1.475(b)(1) states that an international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn to a product and a process specially adapted for the manufacture of said product, and 1.475(b)(2) states that an international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn to product and process of use of said product. In the instant situation, independent claim 1 in Group I is directed to a database comprising information on amino acid sequences of proteins with one or more known biological functions, and further comprising information on importance scores regarding appearance of said biological functions added for each amino acid residue constituting said amino acid sequences. The claims in Group II are dependent claims, depending ultimately upon claim 1 in Group I, and are directed to a method of preparing an alignment of a protein stored in the database according to claim 1 and a polypeptide with unknown biological function. **Accordingly, it is readily evident that the claims of Groups I and II satisfy unity of invention in accordance with 37 C.F.R. 1.475.**